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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BERNHARDT, EMILY B

ART UNIT PAPER NUMBER

1624

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,795

Applicant(s)

LEHMANN-LINTZ ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,13,14 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 is/are allowed.
- 6) ☒ Claim(s) 10,14 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

In view of applicants' response filed 12/18/03 the following applies.

Newly submitted claims 10,14,16-18 (all in part) are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Ra as various heteroaryls requires additional searching in the electronic CAS database as well as in the US Patents System which has not been done in the first office action since claims previously presented for an examination solely required that Ra be phenyl with possible further fusion and substituents thereon. The newly added rings are separately and variously classified in class 544 subclasses such as 295, 357,360,379 and in various subclasses of class 514. Such compounds are made and used independently of each other and may raise additional issues of patentability apart from that previously set forth and maintained below.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, said subject matter in claims 10,14,16-18 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 10,14,16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. In main claim 10 as now amended it should be made clear on p.3 that the biphenyl groups, are alternate choices for R_a . "Or R_a is" Is suggested.
2. In claim 18 on p.7 for the first optional step recited which entails reduction of nitro groups to amino groups, it does not appear that a nitro group is still present within the scope of claim 10 as now amended and thus this step is extraneous.

Claims 10,14,16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The revision in claim 10 to the R_c definition changing to position "2" to "1" lacks descriptive support in the original disclosure. It is not evident from a reading of the original disclosure that this change is to correct an obvious error. See for example, Note Ex parte Bondiou 132 USPQ 356; Ex parte Broadbeck 199 USPQ 230; Ex parte Fox 128 USPQ 157. Applicant is required to cancel the new matter in the reply to this Office action.

Claims 10,14,16-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1.) Reason #2 of the previous action remains notwithstanding applicants' remarks.

While heteroaryls have been deleted from the scope of Rc and Rd, the scope at Ra and Re still contain a variety of hetero rings as substituents thereon that have not been shown will have the requisite activity needed to practice the invention.

Applicants' comment made at the top of p.9 in their response is self-contradictory as an unexpected result is not predictable. If applicants really intended to say that alkoxycarbonyl and cycloalkoxycarbonyl group at Re are solely or mainly responsible for activity , such would not be persuasive since such has not been originally disclosed and applicants have not shown by any examples containing heterocyclic rings that variation of such as substituents in Re and/or Ra is not structure-sensitive to MTP inhibitory activity or deleterious. A similar comment was made by the EP examiner in citing an opinion during the international phase of this application. Also, a similar argument was made in In re Cauvallito 127 USPQ 202- see especially right column on p.205,2nd -last paragraphs and left column of

p.206. Note the following quote taken from Surrey (previously cited) at p.730, left column, second full paragraph: "An applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of similar utility in the others".

2.) In reviewing the claims still pending it is noted that applicants recite "treating" as well as "preventing" in claim 17. While the former is enabled, the latter is not since it is not recognized in the lipid-lowering art that known drugs are able prevent such uses. See Wierzbicki provided with this action or Sircar (US'855), cited by applicants.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10,14 and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cliffe in view of Abou-Gharbia for reasons of record.

Applicants' traverse to this rejection is not persuasive for the following reasons.

It is not the burden of the prior art to show unexpected properties. Once obviousness has been shown, it is applicants' burden to show that instant compounds possess an unexpected property or improvement that is not shared by the prior art compounds. Note In re Best 195 USPQ 430; In re Mod 161 USPQ 281; In re Dillon 16 USPQ 2d 1897. While close compounds in the prior art have

been pointed out for testing, no comparative data with closest instant compounds has been provided. Note again that the closest instant compounds to Cliffe are merely higher homologs. In the case law dealing with homologs there was no teaching to modify the methylene chain yet claims were still refused based on the close structural similarity that existed with the prior art homologs.

With regard to Abou-Gharbia, while the same type of alkyl ester as claimed herein is not taught, said reference was only relied on for showing the one feature of the instant invention not taught by Cliffe, namely the variation of the methylene chain corresponding to instant "n". Such compounds are taught for the same uses as Cliffe and are very structurally similar- being also drawn to alkyl and cycloalkyl ester derivatives of 4-phenyl piperazine derivatives. By their very name secondary references are expected to have some structural differences from what is instantly claimed otherwise they would be primary references or anticipations. The test for obviousness is not whether the elements of one reference can be bodily incorporated into the invention of another but rather what the combined teachings of the references would have suggested to those of ordinary skill in the art.

The 102 rejection is overcome by applicants' amendments which removes H as a choice at Rc.

Claim 13 is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



EMILY BERNHARDT

PRIMARY EXAMINER

Group 1600